

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Quality of Life Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Quality of Life Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

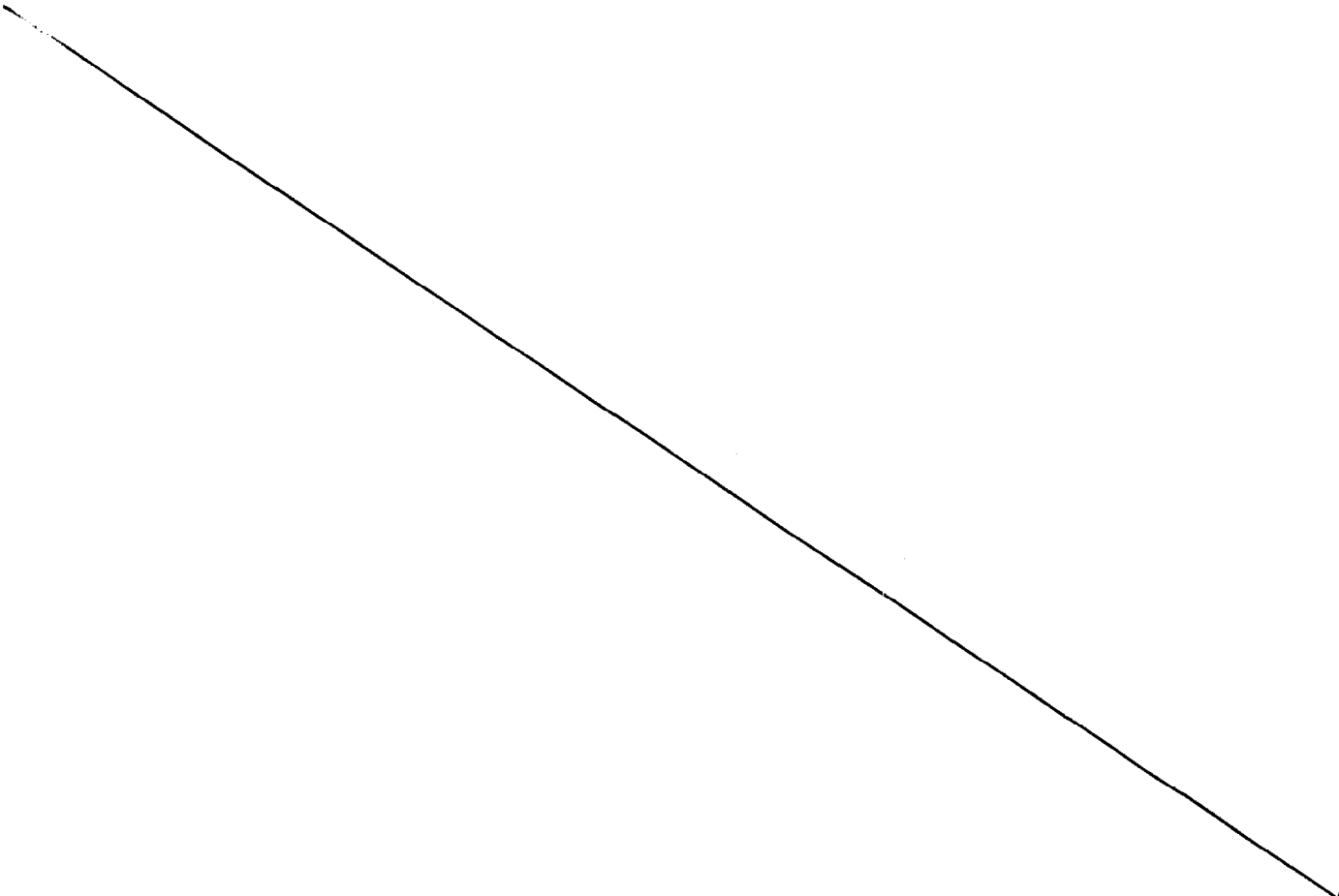
Date and Time: The meeting will be held on February 10, 2000, 8 a.m. to 4 p.m.

Location: Ramada Inn, Embassy Ballroom, 8400 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

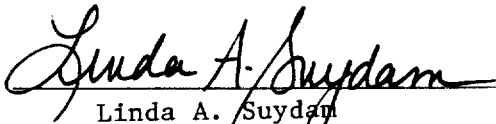
Agenda: The Quality of Life Subcommittee of the Oncologic Drugs Advisory Committee will discuss issues related to the study of quality of life for patients enrolled in cancer trials. Specific potential areas for discussion include definition of patient centered outcomes, clinical significance and interpretation of study results, and approaches to the statistical analysis of data.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 3, 2000. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and between approximately 12:45 p.m. and 1:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 3, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by February 3, 2000, to address issues specific to the topic before the committee.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.
2).

Dated: January 18, 2000



Linda A. Suydam
Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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